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U.S. Army Center For Health Promotion And Preventive Medicine (USACHP 'M)
Strategic Initiatives Office (SIO), Quality Assurance Team (QAT)

STANDING OPERATING PROCEDURE
FOR
FACILITY MASTER SCHEDULE


Preparer

03 JAN 2001
Date


Supervisor Approval

1/4/2001
Date

Annual Review

Preparer

03 JAN 02
Date Due Date Comp.

Supervisor

03 JAN 02
Date Due Date Comp.

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Disclaimer: This Standing Operating Procedure has been prepared for the sole use of the U. S. Army Center For Health Promotion and Preventive Medicine (USACHPPM) and may not be specifically applicable to the activities of other organizations.

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I.	PURPOSE : This standing operating procedure (SOP) describes the procedures for maintaining a copy of the Facility Master Schedule (FMS) in accordance with the Good Laboratory Practice (GLP) regulations.
II.	<u>APPLICABILITY:</u> This SOP applies to all USACHPPM QAT personnel.
III.	<u>DEFINITIONS:</u> None.
IV.	<u>QUALITY CONTROL:</u> This document shall be controlled in accordance with QAT SOP 1.X.
V.	<u>PROCEDURE:</u> It is the responsibility of the DLS toxicology operations area to maintain the FMS current as per SOP # 95. The Facility Master Schedule (FMS) is an on going database consisting of all toxicology studies undertaken by the USCHPPM/DLS. The FMS shall include but not be limited to: <ul style="list-style-type: none">A. Identity of the test substance,B. Test System,C. Nature of study,D. Identity of study director,E. Identity of Sponsor,F. Anticipated start date,G. Anticipated finish date,H. Status of study.

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In accordance with GLP regulations the QAT will maintain a copy of the FMS. The QAT will access the Master Schedule Database (MSD) per instructions in toxicology operations SOP # 95, titled, ≡FACILITY MASTER SCHEDULE DATABASE≡, no less than once per month to obtain the most recent update to the FMS.

A hardcopy report will be printed using the instructions found in the same SOP (toxicology operations SOP # 95). The hardcopy report will be filed in the QAT office. Periodic assessments will be performed by the QAT to ensure that the FMS is maintained current in accordance with the GLP regulations. A report of the assessment findings will be generated in accordance with the quality assurance QAT SOP #3.X, AREPORTING TO MANAGEMENT≡.

- VI. SAFETY CONSIDERATION: Consideration shall given to all possible safety hazards when performing QAT duties.
- VII. 6. REFERENCES:
 - A. USFDA Federal Food, Drug and Cosmetic Act (FFDCA); 21 CFR 58 (1979), latest edition.
 - B. USEPA Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); 40 CFR 160 (1984), latest edition.
 - C. USEPA Toxic Substances Control Act (TSCA); 40 CFR 792 (1983), latest edition.
 - D. Toxicology operations SOP #95, AFACILITY MASTER SCHEDULE DATABASE≡, most current version.
 - E. QAT SOP #3.X, AREPORTING TO MANAGEMENT.≡